K130140

510(k) SUMMARY

AUG 1 2013

Submitter's Name:	Intra-Lock® International 6560 West Rogers Circle Boca Raton, FL 33487
Phone:	(561) 447-8282
Facsimile:	(561) 447-8283
Contact Person:	Diana Taylor
Date Prepared:	July 30, 2013
Name of Device:	Intra-Lock® OP Dental Implants
Common Name:	Dental Implant
Classification Name:	Implant, Endosseous, Root-Form
Classification:	Class II
Regulation Number:	872.3640
Product Code:	DZE
Predicate Devices:	K052997 & K062281 Zimmer® One-Piece Implant K050970, MILO® Implant System, K103194, Intra-Lock® Implant System with Blossom™
Description	The Intra-Lock® OP Dental Implants are threaded dental implants diameter 3.0mm, 3.75mm, 4.0mm and 4.75mm, with an integrated straight abutment (implant and abutment are one piece).
Intended Use:	The 3.0mm Intra-Lock® OP Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. They are also indicated for the rehabilitation of single or maxillary lateral incisors and mandibular lateral and central incisors. Multiple implants may be restored after a period of delayed loading or placed in immediate function when good primary stability is achieved with appropriate occlusal loading in order to restore normal teeth function. 3.75mm, 4.0mm and 4.75mm Intra-Lock® OP Dental Implants: Intra-Lock® Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.
Performance Testing:	The following was reviewed to support performance of the Intra-Lock® OP Dental Implants for their intended use: risk analysis, shelf life and sterilization validation, surface analysis and static / dynamic fatigue.

Substantial Equivalence:

The Intra-Lock® Op Implant and Zimmer® One-Piece Implants both have machined abutments that include design features to mate with instrumentation and utilize the same principals of operation. All the predicates have the same or similar materials, intended use, indications, sterilization and shelf life as the Intra-Lock® OP Implants. The substantial equivalence summary table follows:

	Proposed OP Implants 3.0mm 3.75mm, 4.0mm & 4.75mm	Zimmer ® One-Piece, K052997 - 3.0mm & 3.7mm K062281 - 4.7mm	Intra-Lock MILO® 3.0mm Implants, K050970	Intra-Lock® Dental Implant System with Blossom™, K103194
Material	TI6AL4V, CP Titanium	Titanium Alloy	TI6AL4V	TI6AL4V, CP Titanium
Surface	Blasted	Zimmer MTX Surface	Blasted	Blasted
Thread Patterns	- 3.0mm, wide pitch, no cutting flutes - 3.75mm wide pitch w/ cutting flutes - 4.0mm & 4.75mm Blossom All designs feature horizontal micro threads	cutting flute on the apical end no horizontal micro threads	Wide pitch, no cutting flutes, horizontal micro threads	Blossom = at least one cutting surface on each thread and horizontal micro threads.
Design sizes	3.0mm,3.75mm 4.0mm& 4.75mm dia.; 10mm – 15mm lengths	3.0mm dia, 10-13mm lengths 3.7mm & 4.7mm dia.; 10 - 16mm lengths	3.0mm, O-Ball implant 10mm – 15mm lengths	3.5mm, 4.0mm (& 6.0mm) dia; 8mm – 15mm lengths
Abutment	Straight abutment machined on implant	Straight abutment machined on implant	Abutments cemented	Screw retained abutments via internal connection
Principals of Operation	Machined abutment has mating features so the design specific driver fits directly over the abutment for pick up, delivery (placement) and final seating. The OP transfer is snapped over the abutment to be picked up in the impression. The OP analog is inserted into the transfer prior to creating the working model.	Instrumentation engage the implant externally to pick up deliver and seat the implant. The impression cap snaps over the abutment, and picked up in the impression. The analog replicates the Zimmer One-Piece Implant in the stone model.	Instrumentation fits over the O-Ball for pick up, delivery and final seating. MILO impression coping snaps over the O-Ball to be picked up in the impression. The MILO analog is inserted into the transfer prior to creating working model.	Instrumentation pick up the Blossom implant via hex configuration which mates with the internal connection of the implant. A screw retains the impression coping. Analogs are placed in the transfer and secured with screw.
Intended use	The 3.0mm Intra-Lock® OP Dental Implants are indicated for long-term maxillary and mandibular tissue-supported denture stabilization. They are also indicated for the rehabilitation of single or maxillary lateral incisors and mandibular lateral and central incisors. Multiple implants may be restored after a period of delayed loading or placed in immediate function when good primary stability is achieved with appropriate occlusal loading in order to restore normal teeth function. 3.75mm, 4.0mm and 4.75mm: Intra-Lock® Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.	Zimmer One-Piece 3.0mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restorations in the mandibular central and lateral incisor and maxillary lateral incisor regions of partially edentulous jaws. The Zimmer one-piece 3.0mm implant must be splinted if two or more are used adjacent to each other. The Zimmer One-Piece 3.0mm implant may be immediately restored with a temporary prosthesis that is not in functional occlusion. Zimmer One-Piece 3.7mm & 4.7mm implants are indicated for the support and retention of fixed single tooth and fixed partial denture restoration in the premolar, cuspid and incisor regions of partially edentulous jaws. Zimmer one-piece implants may be loaded immediately in the anterior mandibular arch if four are splinted together with a bar. The Zimmer one-piece implant may be immediately restored with a temporary prosthesis that is not in functional occlusion.	MILO® Dental Implants are indicated for long-term maxillary and mandibular tissue supported denture stabilization. They are also indicated for the rehabilitation of single or maxillary lateral incisors and mandibular lateral and central incisors. Multiple implants may be restored after a period of time or placed in immediate function.	Intra-Lock® Implants have been designed to restore partially or fully edentulous patients. The implants have been designed to be used in either the mandible or the maxilla and to support removable or fixed prostheses, from single tooth replacement to full arch reconstruction. Intra-Lock® Implants are intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore normal teeth functions.
Sterilization	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Shelf Life	5 years	5 years	5 years	5 years

Conclusion:

The comparison confirms that the Intra-Lock® OP Implants are substantially equivalent to the predicate devices. The minor differences between these designs and principals of operation raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2013

Intra-Lock® International, Incorporated
Ms. Diana Taylor
Regulatory Affairs Manager
6560 West Rogers Circle, #24
Boca Raton, FL 33487

Re: K130140
Trade/Device Name: Intra-Lock® OP Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: June 28, 2013
Received: July 1, 2013

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130140

Device Name: Intra-Lock® OP Dental Implants

Indications for Use:

For 3.0mm Intra-Lock® OP Dental Implants:

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Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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